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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,423	02/25/2004	Allen Wayne Mangel	PG3731US2	2803

23347 7590 11/23/2005

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EXAMINER
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SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/786,423

Applicant(s)

MANGEL ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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Applicants' Amendment filed September 13, 2005 is acknowledged. Claims 22-25 remain under consideration.

The rejection of record in the last Office Action of claims 22-25 under 35 U.S.C. 112, second paragraph, is withdrawn following the deletion of the term "derivative" in the claims and insertion of -- salt or solvate -- therefor.

Subsequent to the submission of terminal disclaimers over Patent 6,759,413, 6,831,097 and 6,780,870, the rejections of record in the last Office Action under the judicially created doctrine of obviousness-type double patenting are withdrawn.

Applicants are requested to send a complete list of co-pending and related applications for the inventors when responding to this Office Action.

In the last Office Action claims 22-25 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to practice the invention. It was asserted non-ulcerative dyspepsia broadly encompasses the inability to digest or a difficulty in properly digesting food in the alimentary tract and the abdominal discomfort or illness that results from this inability or discomfort. Various motility disturbances, as well as reflux disease, are non-ulcerative dyspeptic conditions.

Applicants argue the beagle dog is a recognized model for studying gastrointestinal disorders in humans and evaluating gastric emptying is an art-recognized model for evaluating efficacy for the treatment of NUD. Further, Applicants urge that a showing that COX-2 inhibitors both enhance gastric emptying and increase lower esophageal pressure has been set forth.

Favorable consideration would be given those methods of treating nonulcerative dyspeptic conditions wherein, following the administration of a COX-2 inhibitor, a significant stimulation in gastrointestinal transit time, an increase in lower esophageal sphincter pressure and an increase in gastric emptying are observed.

The rejection of record under 35 U.S.C. 112, first paragraph, is maintained.

Claims 22 and 24 were rejected in the last Office Action under 35 U.S.C. 102(a) as being anticipated by Morgan, G., European Journal of Gastroenterology and Hepatology. It was asserted Morgan teaches the administration of selective COX-2 inhibitors for reflux esophagitis.

Applicants argue there is no showing that the condition of reflux esophagitis would be inclusive of NUD.

The rejection is withdrawn because Morgan does not teach all limitations of claims 22 and 24.

In the last Office Action claims 22-25 were rejected under 35 U.S.C. 103 as being unpatentable over Morgan, G., European Journal of Gastroenterology and Hepatology.

Morgan suggests the beneficial administration of COX-2 inhibitors for treatment of motility disorders of various etiologies and in the treatment of gastroesophageal reflux disease, both of which are not characterized by inflammation.

Applicants' argument that Morgan's teaching is nothing more than an invitation to experiment is not persuasive. Motility disturbances, such as reflux disease, are non-ulcerative dyspeptic conditions. The rejection is maintained.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire **THREE MONTHS** from the mailing date of this Action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink that reads "Phyllis Spivack". The script is cursive and fluid, with the first name "Phyllis" and last name "Spivack" clearly distinguishable.

Phyllis Spivack

November 19, 2005

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**